Quality Assurance In HIV Testing

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CDC Model Performance Evaluation Program

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definitions...

Quality Assurance

- Quality Assessment
- Quality Control
- External Quality Control

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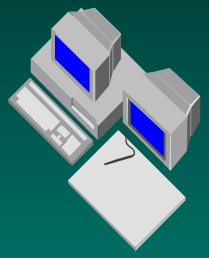
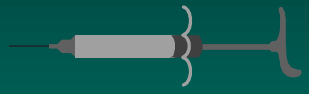
The Testing Process

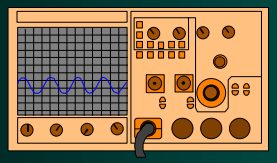
Need



Order



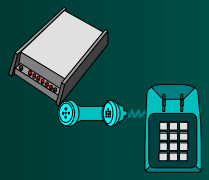
Collect



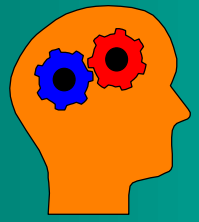
Prepare

Transport

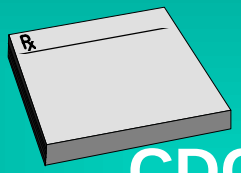
Analysis



Report



Act



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The Testing Process

Pre-Analytic

- test order
- spec. collection
- spec. transport
- spec. processing
- spec. storage

Analytic

- select method
- verify test performance
  - sensitivity
  - specificity
  - reportable range
- reference range

Post Analytic

- validate results
- report timely

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Quality Assurance Elements

- **personnel training & competency**
- **quality monitoring process**
  - specimen collection & manipulations
  - test procedures validation
  - quality control
  - results evaluation & reporting
- **proficiency testing/performance evaluation**
- **inspection process**

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Quality Assurance:

- The sum of all laboratory activities to ensure that the final reported test results are correct.
- a dynamic and ongoing process
- monitors steps in the total testing process

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Quality Control:

- Procedures performed by the laboratory to ensure that the testing process is working properly to produce accurate and reliable results
- validation of testing results
- contol for random errors
- detect potential problems

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Quality Assessment:

- Processes to determine the quality of results reported by the laboratory
- proficiency testing programs
- performance evaluation programs

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External Quality Control:

- Well characterized serum/plasma different than material provided by kit manufacturer
- determines test kit lot-to-lot variability
- assists in ensuring reproducible results

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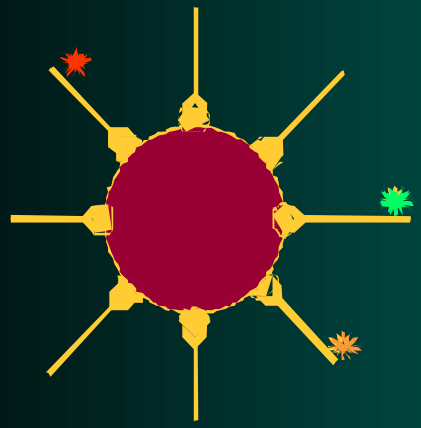
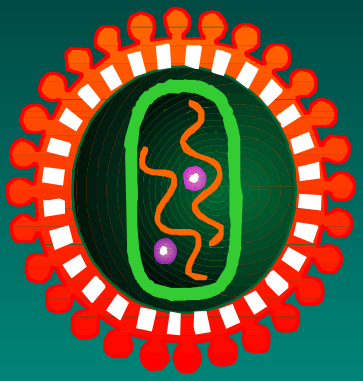


MPEP

Model Performance Evaluation Program



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Reasons For Implementing The Model Performance Evaluation Program

- Assess laboratory testing performance
- Identify errors in the testing process
- Provides laboratories with opportunities for self-assessment

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Reasons For Implementing The Model Performance Evaluation Program

- Monitor new technology and changes in current technology
- Learn more about the laboratory testing process
- Establish national data base of laboratory characteristics and testing practices

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Model Performance Evaluation Program:

- Voluntary - Non Regulatory
- Free of charge
- Research program
- Determines factors affecting testing quality

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Model Performance Evaluation Program:

- Aggregate reports of results
- May determine procedural problems
- Achieve/Maintain high quality testing

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MPEP Performance Surveys

Program	Survey Frequency	No. of Samples	Sample Characteristics*
HIV-Ab	2/yr	6 (plasma)	HIV-Ab-strong /weak positive HIV-Ab-negative
HTLV-Ab	2/yr	6 (plasma)	HTLV-Ab-positive/Ab-negative
TLI	2/yr	5 (whole blood)	HIV-Ab-positive/Ab negative
HIV RNA	2/yr	6 (plasma)	HIV-RNA positive/RNA negative
HIV p24 Ag	2/yr	6 (plasma)	HIV-Ag-positive/Ag negative

*Unaltered, Undiluted, Individual Donor Material

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Model Performance Evaluation Program:

- Strong positive, negative, weak positive samples/specimens
- Duplicate samples/specimens per shipment
- Identical samples from the same donors between replicate shipments (HIV, HTLV, RNA, p24 Ag)

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MPEP
Survey Questionnaires

Survey	Frequency
Retroviral	Biennially
TLI Laboratory	Annually

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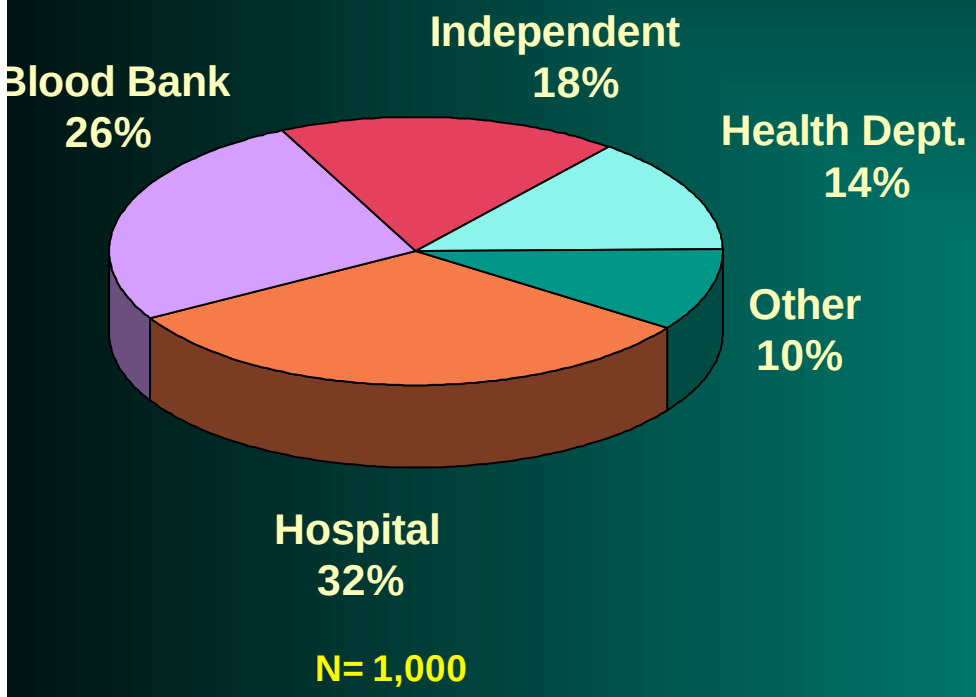
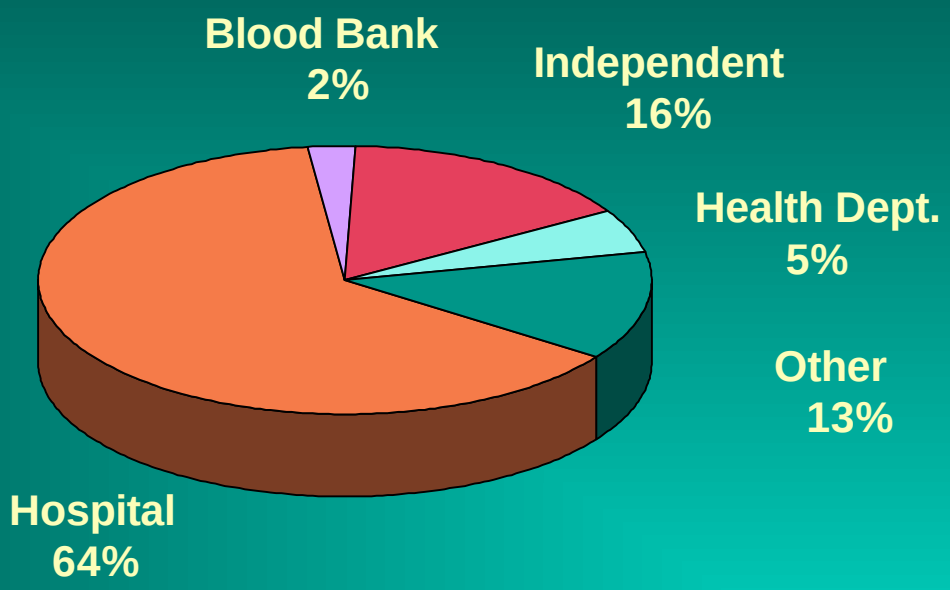
MPEP Participant Laboratory Types

HIV Antibody Testing



N= 1,000

CD4+ T-Cell Testing



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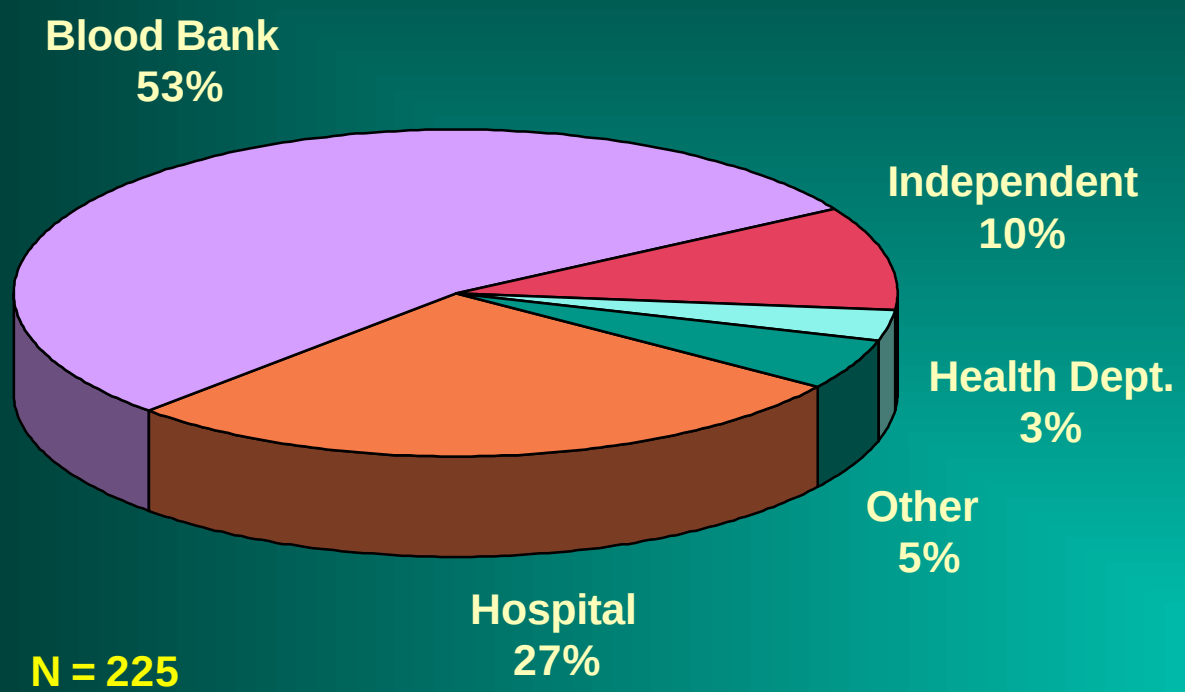
MPEP Participant Laboratory Types



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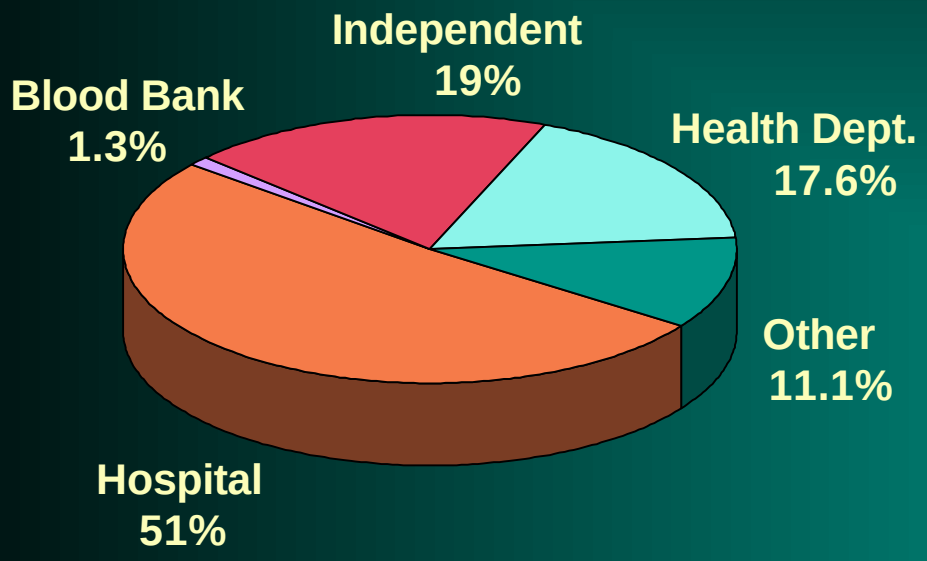
MPEP Participant Laboratory Types

HIV-1 RNA Testing



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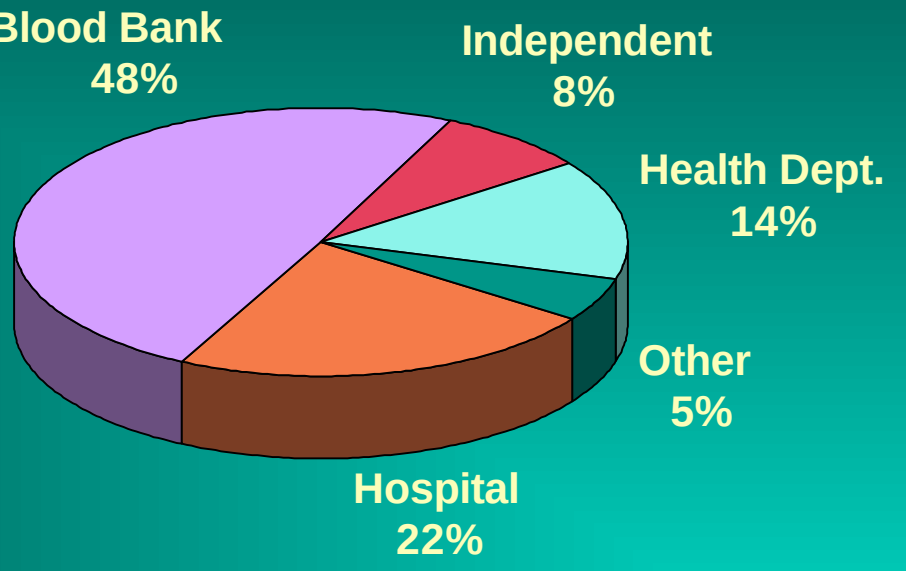
HIV-1 p24 Ag Testing



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Percentage of MPEP Laboratories Using ASTPHLD/CDC Western Blot Interpretive Criteria

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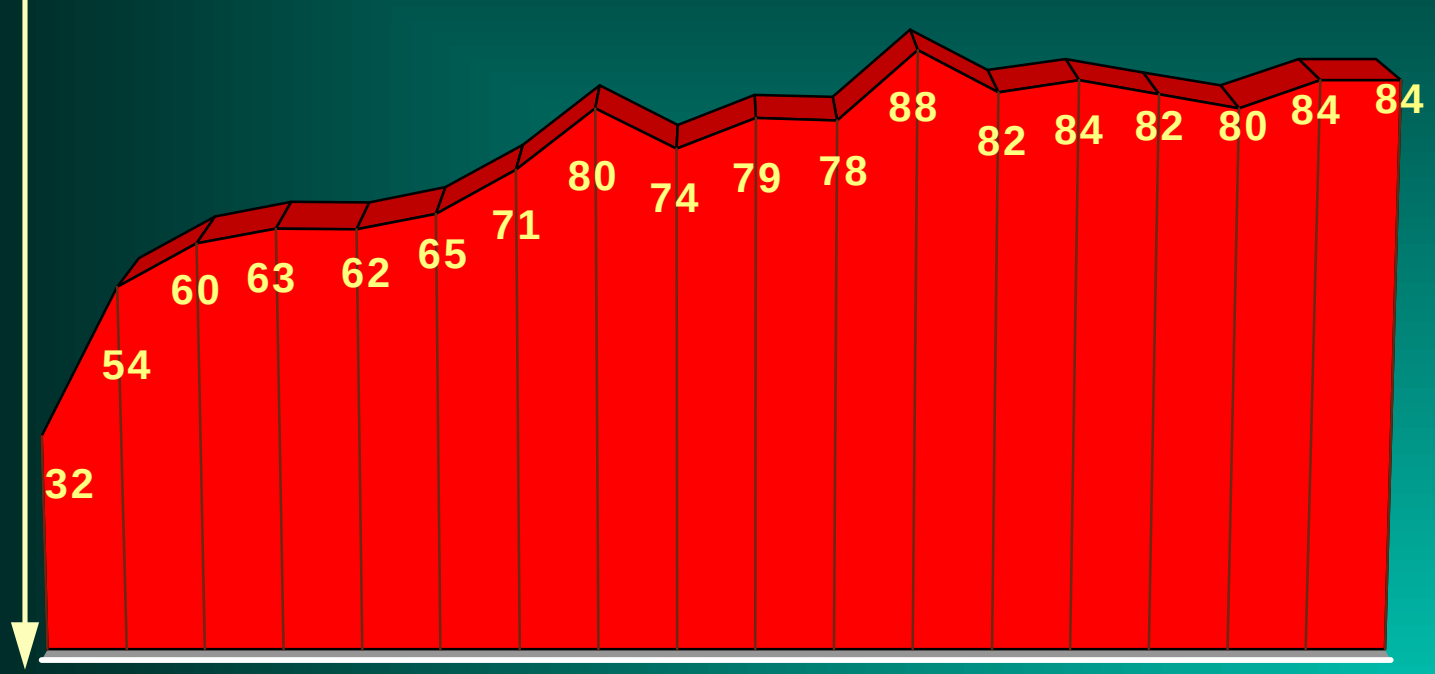
MMWR
July 1989



08	11	02	05	09	02	07	02	08	02	07	02	08	01	08	01	08	01
89	89	90	90	90	91	91	92	92	93	93	94	94	95	95	96	96	97

Month
Year

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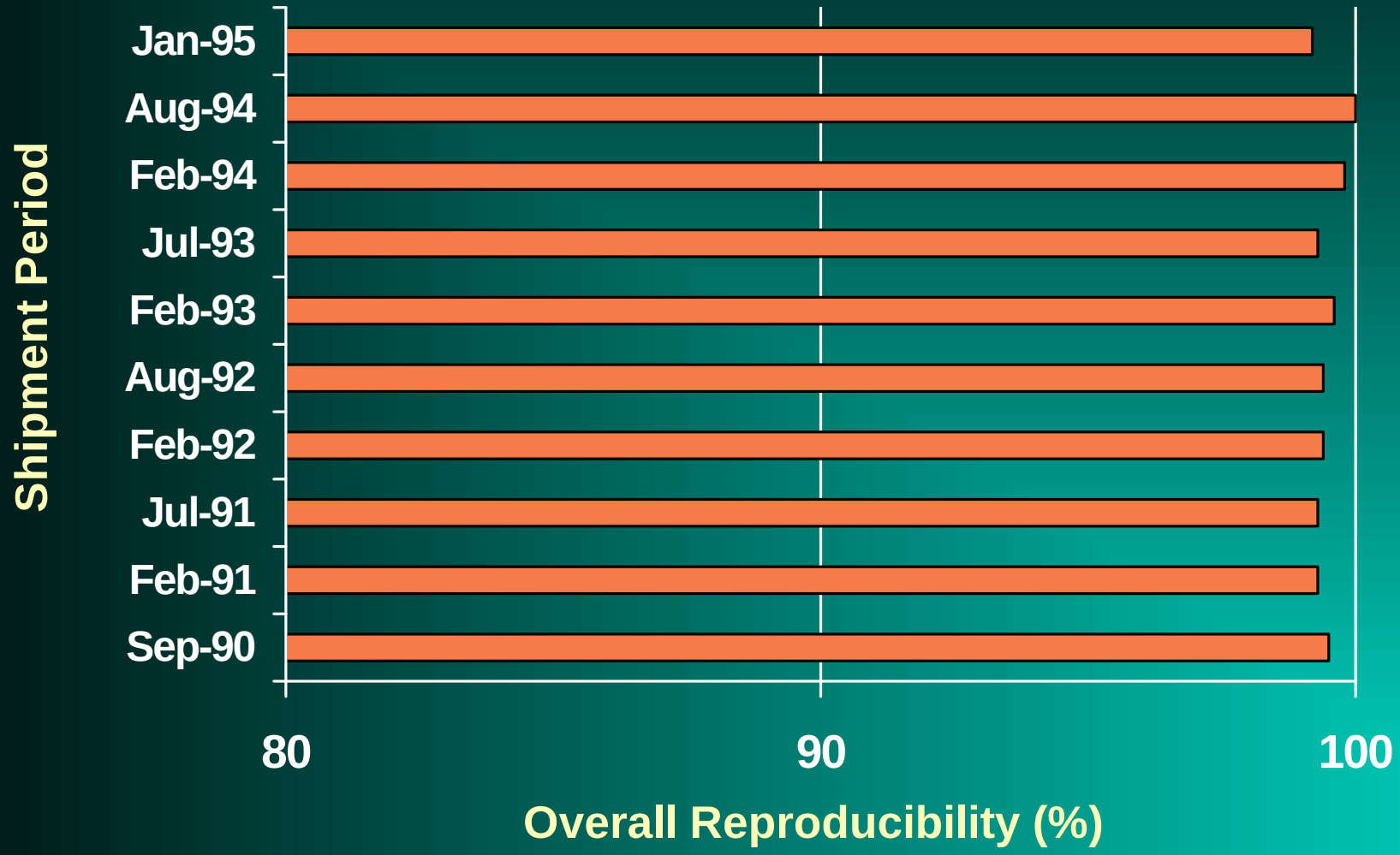
Enzyme Immunoassay Intrashipment Reproducibility



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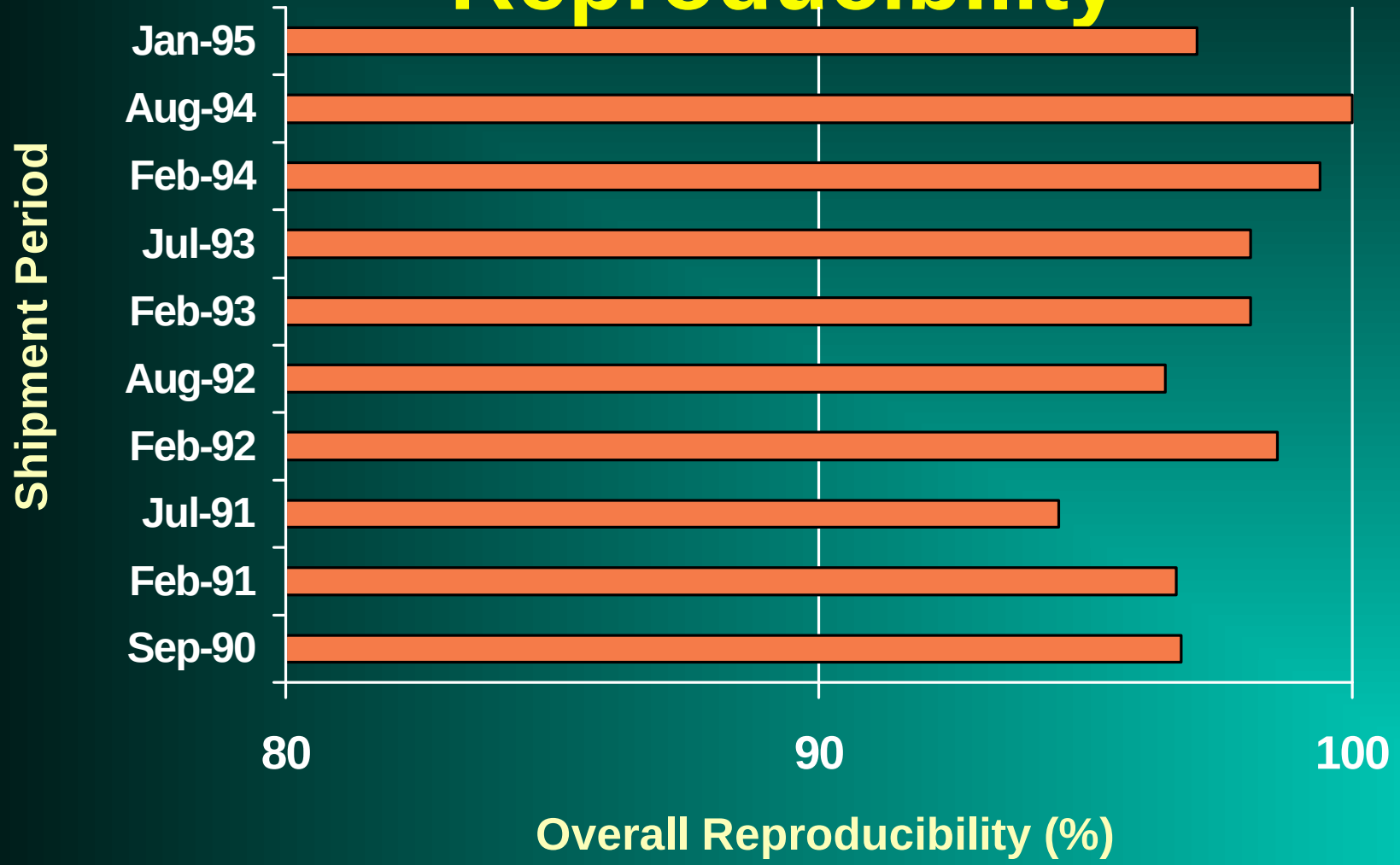
Western Blot Intrashipment Reproducibility



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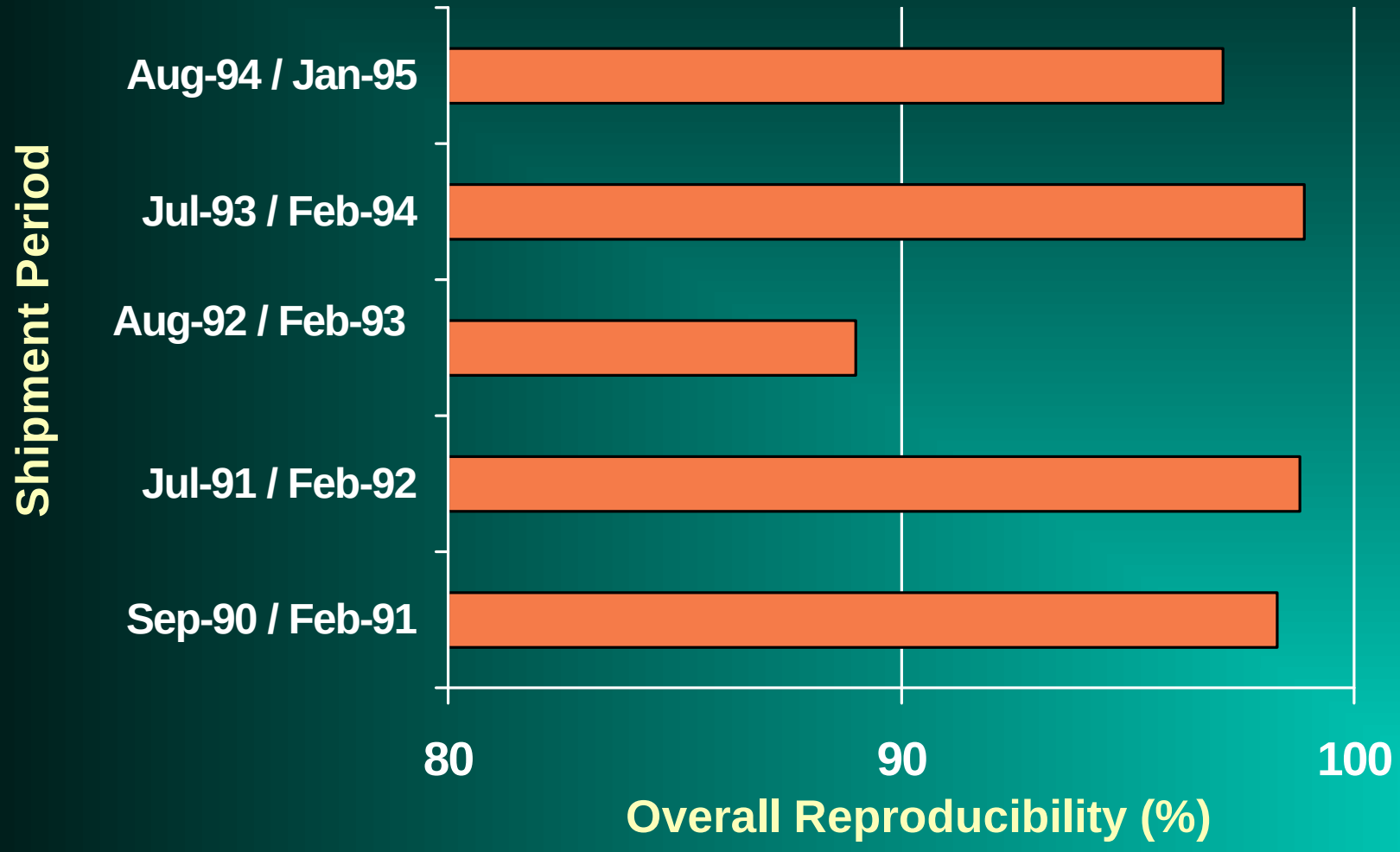
Enzyme Immunoassay Intershipment Reproducibility



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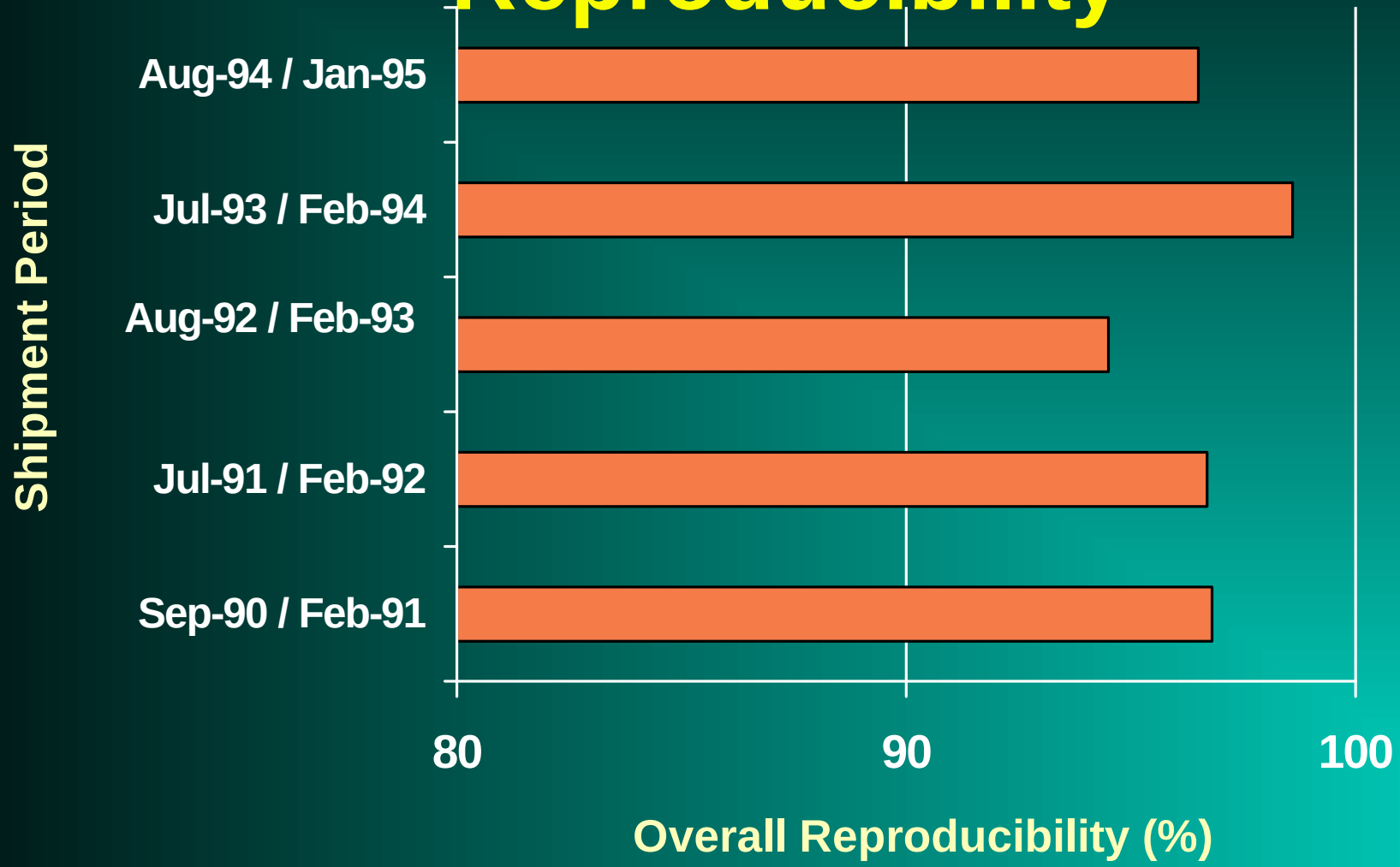
Western Blot Intershipment Reproducibility



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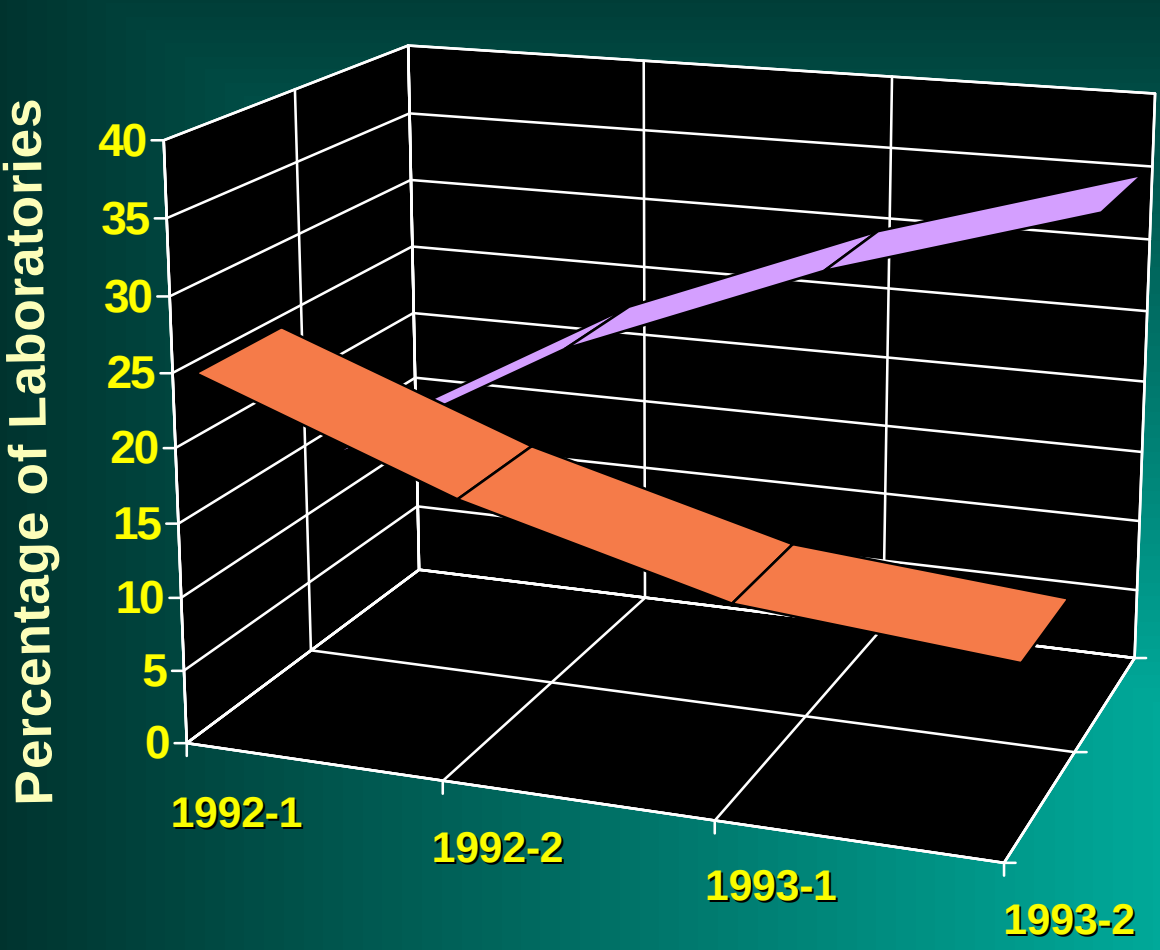
TLI Laboratories Using MMWR Guidelines



Comply with more than 80%

Comply with less than 60%

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HIV-1 RNA Testing Results

Results Reported

Donor Type	RNA Detected	RNA Not Detected
RNA-Positive	491 (97.8%)	11 (2.2)%
RNA-Negative	9 (2.7%)	329 (97.3%)

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Annual Estimated Retroviral and AIDS-Related Testing

Laboratory Type	Screening Tests	Supplemental Tests	HIV-Antigen Tests	CD4 T-Cell Tests
Blood Bank	11,602,708	49,660	218,972	8,774
Hospital	1,061,528	30,472	28,028	198,327
Independent	8,646,820	217,008	92,716	511,440
Heath Dept.	4,629,584	133,472	48,620	10,851
Other	8,337,160	79,924	254,748	96,630
Totals	34,340,800	510,536	643,084	826,022
Projected Estimates (US)	40 - 45 M	625 - 650 K	800 - 804 K	1.2 - 1.25 M

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A Model for Quality Control

major contributors to testing errors...

- test system / technology
- environmental factors
- testing personnel

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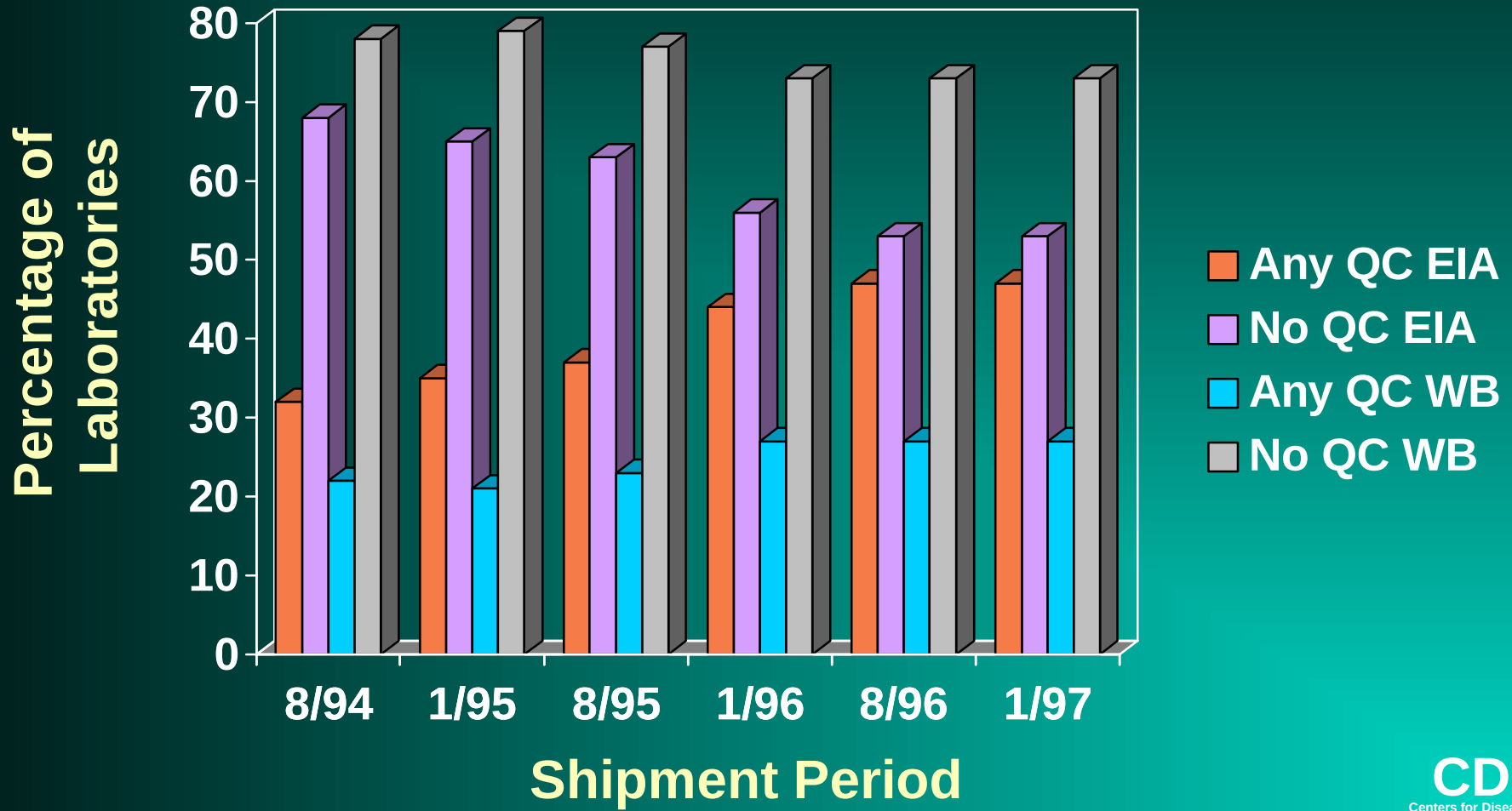
Use of External QC Material for HIV-Antibody Testing



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Study Design

- **Study population: HIV labs in MPEP**
  - Voluntary participation
  - Approximately 600 U.S. labs per survey
  - Panel of 6 “patient” samples per lab per survey
  - 5 surveys (Aug 94 - Aug 96)
- **Dependent variable: accuracy in testing the MPEP samples for HIV Ab by EIA (n = 18,600 results)**

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External QC Use by Laboratory Type

Lab Type	Labs tested	Percentage Using External QC
Blood Banks	736	23%
Hospital	1148	41%
Independent	609	35%
Health Dept.	451	64%
Other	156	44%
Total	3100	Average 39%

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MPEP Error Rates

Survey	Errors	Error Rate
9408	92	2.8%
9501	116	3.0%
9508	58	1.5%
9601	171	4.5%
9608	53	1.4%
Total	490	2.6%

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Univariate Results

- **24% reduction in the error rate when using external QC (p= 0.0047, 95% CI: 8%, 37%)**

	Incorrect result	Correct result	Total
Used QC	160 (2.2%)	7076 (97.8%)	7236 (38.9%)
Didn't Use	330 (2.9%)	11034 (97.1%)	11364 (61.1%)
Total	490 (2.6%)	18110 (97.4%)	18600

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Multivariate Results

- Using external QC lowered the error rate by an average of 31% (p=0.0002, 95% CI: 15%, 44%)
- Lab type did not affect the error rate
- Impact of QC varied with assay manufacturer

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Conclusions

- Quality Assurance activities are necessary to monitor the total testing process
- Quality Assessment activities (MPEP) can assist in identifying testing problems and maintaining high quality testing
- Quality Control procedures can ensure accurate and reliable results

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